

REMARKS

Claims 22-42 are pending in the instant application. Claims 22, 31 and 38 are amended. Claims 1-21 have been cancelled previously. Support for the amendments may be found in the Specification at page 16, line 22 to page 17, line 18, for example. No new matter is submitted. Accordingly, entry and consideration of the Amendment is respectfully requested.

Applicants appreciate the clarification of claims 22-42 as pending, the rescinding of the finality of the previous Office Action, and the acknowledgment and entry of the Terminal Disclaimer filed with the previous Amendment in this application.

At pages 2-3 of the Office Action, claims 22-30 are rejected under 35 U.S.C. 102(e) as allegedly anticipated by U.S. Patent No. 5,738,626 to Jarvik (hereafter “Jarvik”). The rejection is respectfully traversed.

To maintain a 35 U.S.C. 102 rejection, a reference must teach each and every claimed element. Jarvik does not do so.

Applicants’ independent claim 22 recites, a method of reshaping a patient’s heart comprising inserting a thorascopic measurement device into the chest of a patient, the thorascopic measurement device comprising a shaft having an inner lumen and a flexible band extending therefrom; gauging a size of a left ventricle via the thorascopic measurement device; determining an amount by which the left ventricle should be reduced from the gauging of its size; and reducing a dimension of the left ventricle in accordance with the determined amount.

Jarvik discloses a method for excising a portion of a dilated left ventricle and supporting the left ventricular function via a cardiomyoplasty muscle wrap (col. 3, lines 25-28). The Office Action concedes that Jarvik is silent with respect to any gauging of the left ventricle size is accomplished. Jarvik thus fails to teach or disclose inserting a thorascopic measurement device

into the chest of a patient in order to gauge the size of the left ventricle, the thorascopic measurement device comprising a shaft having an inner lumen and a flexible band extending therefrom, as recited in Applicants' independent claim 22. Accordingly, Jarvik fails to teach or disclose each and every feature recited in at least Applicants' independent claim 22, from which claims 23-30 ultimately depend. Withdrawal of the 35 U.S.C. 102(e) rejection of claims 22-30 is thus respectfully requested.

At pages 3-6 of the Office Action, claims 22-42 are rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Derek Gordon 1997 (Publication: "Too Big a Heart" in which a cardiac reduction procedure known as the "Batista procedure", based on the theories and practices of Dr. Randas Jose Vilela Batista in Brazil, is discussed) (hereafter "Gordon") in view of U.S. Patent No. 5,613,302 to Berman (hereafter "Berman") and/or either of U.S. Patent No. 4,624,671 to Kress (hereafter "Kress") or U.S. Patent No. 5,814,098 to Hinnenkamp, et al. (hereafter "Hinnenkamp"). The rejection is respectfully traversed.

Applicants' independent claims 22, 31 and 38 each recite a method of reshaping a patient's heart. In particular, claim 22 recites a method of reshaping a patient's heart comprising, *inter alia*, gauging a size of a left ventricle via a flexible band extending from a shaft of a measurement device as discussed previously above. Claim 38 recites a method of reshaping a heart comprising, *inter alia*, gauging a size of a heart with an adjustable length band extending from the shaft of a measurement device. Claim 31 recites a method of reshaping a heart comprising, *inter alia*, introducing an expansible member through a chest port and into a left ventricle via a mitral valve, and then expanding the expansible member to determine the volume of the left ventricle. In each case, the size of the heart gauged by the methods recited in independent claims 22, 31 and 38 determines an amount by which the left ventricle is reduced.

Gordon, a July, 1997 internet publication, discloses very generally the cardiac reduction procedure (the “Batista procedure”) that excises chunks of muscle from the heart in order to more nearly approximate a muscle mass to heart diameter proportion characterized as “a perfect proportion” based on the law of La Place: $\text{mass} = 4 \times \text{radius}^3$. The Batista procedure thus determines how much muscle tissue to excise based on the ratio of mass relative to the diameter of the heart. Gordon thus determines an overall size of the heart relative to an overall mass of the heart, but nowhere discloses, suggests or infers any steps, tools, or calculations used to determine the size of a specific chamber of the heart based on the overall heart size or mass. Nor does Gordon mention the tools or techniques used in making such mass and diameter determinations. Rather, Gordon discloses only that the Batista procedure determines the proportion of the mass of the heart to the diameter of the heart. In particular, Gordon fails to teach, disclose or suggest inserting a measurement device comprised of a shaft and a flexible band extending therefrom for determining the size of a heart, as recited in Applicants’ independent claim 22. Gordon similarly fails to teach, disclose or suggest inserting a measurement device comprised of a shaft and an adjustable band extending therefrom for determining the size of a heart, as recited in Applicants’ independent claim 38. Gordon also fails to teach, disclose or suggest introducing an expansible member through a chest port and into a left ventricle of the patient’s heart via a mitral valve, and then expanding the expansible member to determine the size of a heart, as recited in Applicants’ independent claim 31.

Berman discloses an external circumferential waist measuring device 10, and thus fails to overcome the deficiencies of Gordon with respect to the internally received measurement device and band recited in each of Applicants’ independent claims 22 and 28.

Hinnenkamp discloses an adjustable sizing apparatus 500 including an expansible member 508 for sizing an annulus to accommodate implantation of a heart valve. Hinnenkamp, however, fails to teach or suggest inserting said apparatus and expansible member through a chest port and into a left ventricle of a heart through a mitral valve, as recited in Applicants' independent claim 31.

Kress discloses a method of sizing a breast prosthesis using a balloon expansible member 6 that is inserted through an incision 2 and into a cavity behind a breast 4, and filled to determine the size the breast prosthesis should be (col. 3, lines 14 –18). Thus, neither Hinnenkamp nor Kress teach or suggest introducing an expansible member through a chest port and into a left ventricle via a mitral valve, and then expanding the expansible member to determine the volume of the left ventricle, as recited in Applicants' independent claim 31.

Thus, Gordon in combination with Berman fails to teach or suggest the combination of features recited in Applicants' independent claims 22 and 38, from which claims 23-30 and 39-42, respectively, depend. Further, Gordon in combination with Hinnenkamp and Kress fail to teach or suggest the combination of features recited in Applicants' independent claim 31, from which claims 32-37 ultimately depend. Accordingly, withdrawal of the 35 U.S.C. 103(a) rejection of claims 22-42 based on the combination of Gordon in view of Berman and/or either of Hinnenkamp and Kress is respectfully requested.

At page 6 of the Office Action, claims 31-42 are rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Jarvik in view of Berman and Kress or Hinnenkamp. The rejection is respectfully traversed.

Applicants' independent claim 31 recites a method of reshaping a heart comprising, *inter alia*, introducing an expansible member through a chest port and into a left ventricle via a mitral

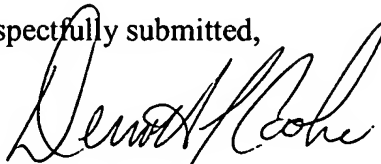
valve, and then expanding the expansible member to determine the volume of the left ventricle. Claims 32-37 depend from claim 31. Applicants' independent claim 38 recites a method of reshaping a heart comprising, *inter alia*, gauging a size of a heart with an adjustable length band extending from the shaft of a measurement device. Claims 39-42 depend from claim 38. In each case, the size of the heart gauged by the methods recited in independent claims 31 and 38 determines an amount by which the left ventricle is reduced.

Jarvik is discussed above. Likewise, Berman, Kress and Hinnenkamp are discussed above. Neither of Jarvik, Berman, Kress, and Hinnenkamp, singly or in any combination thereof, teach, disclose or suggest the combination of features recited in Applicants' independent claims 31 and 38, from which claims 32-37 and 39-42 respectively depend. In particular, Jarvik and Berman fail to teach or suggest insertion of a measurement device comprised of an adjustable band to determine the size of a heart, as recited in Applicants' independent claim 38. Moreover, the combination of Jarvik and Hinnenkamp and Kress fail to teach or suggest introducing an expansible member through a chest port and into a left ventricle via a mitral valve, and then expanding the expansible member to determine the size of a heart, as recited in Applicants' independent claim 31. Accordingly, withdrawal of the 35 U.S.C. 103(a) rejection of claims 31-42 based on the combination of Jarvik, Berman, Kress and Hinnenkamp is respectfully requested.

Applicants respectfully submit, therefore, that all claims recite patentable subject matter. Reconsideration of the application and a prompt indication of the allowability of the claims is thus respectfully solicited. If the Examiner determines that anything further is desirable to place

this application in even better form for allowance, the Examiner is invited to contact the undersigned at his earliest convenience.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Dermott J. Cooke". The signature is fluid and cursive, with the first name "Dermott" being more prominent.

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